

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

TINA BURRIS,

CASE NO. 3:20 CV 1450

Plaintiff,

v.

JUDGE JAMES R. KNEPP II

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND
ORDER**

INTRODUCTION

Plaintiff Tina Burris brought this action against Defendants Ethicon, Inc., and Johnson & Johnson under the Ohio Products Liability Act. After a trial on Plaintiff's failure-to-warn claim, a jury found for Defendants. The Court entered final judgment in favor of Defendants on July 21, 2022.

Currently pending before the Court is Plaintiff's timely-filed Motion for New Trial pursuant to Federal Civil Rule 59(a). (Doc. 257). Defendants opposed (Doc. 259) and Plaintiff replied (Doc. 260).

For the following reasons, the Court denies Plaintiff's Motion.

BACKGROUND

This was a products liability case about Defendants' pelvic mesh product, the Prolift, which was designed to treat pelvic organ prolapse. Plaintiff underwent implantation of the Prolift in August 2008 with her physician, Dr. Desrene Brown. Plaintiff asserted she suffered various severe physical injuries from the product and that Defendants failed to adequately warn of the risks of those injuries.

Plaintiff's claim is governed by the Ohio Products Liability Act. Ohio Revised Code § 2307.76 provides:

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

* * *

(B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

Ohio Rev. Code § 2307.76.

In the instant case, the jury found the risks of the Prolift device which Plaintiff claimed caused her injuries were not a matter of common knowledge among physicians who perform pelvic floor surgery, but the Prolift was not defective in its warnings. *See* Doc. 250. The jury therefore found in favor of Defendants. *Id.*

Plaintiff contends the admission of a defense exhibit was so prejudicial it warrants a new trial. The exhibit at issue is Defendants' Exhibit 1156, the Gynecare Surgeon's Resource Monograph ("Monograph"). The Monograph contains, *inter alia*, information regarding potential risks and complications of the Prolift product.

The Monograph was referenced during the testimony of Plaintiff's implanting physician, Dr. Desrene Brown (Tr. 864-68, 873-75, 878-80, 916-20).

Dr. Brown testified she received training on the Prolift in April 2008 (Tr. 860), and she did not recall having seen the Monograph before. *See* Tr. 865 ("I said I don't remember this specific paper. If you have some kind of a sign-in sheet that says I got it, then of course, I got it. But this specific thing, I don't. . . . I don't remember getting this, no."); *see also* Tr. 868 ("I don't remember ever seeing this paper."); Tr. 879 ("Q: And although I think you may have said when you looked at it, I don't remember seeing this, that doesn't mean that Ethicon did not make it available at the training you attended, right?" A: "No". Q: "You don't remember one way or another." A: "That's correct.").

As discussed in greater detail below, the Monograph was then introduced into evidence through Dr. Larry Sirls (Tr. 1139-45) and further discussed by Dr. Salil Khandwala (Tr. 1460-61, 1472-78, 1531, 1550-64).

STANDARD OF REVIEW

A federal court hearing a case on the basis of diversity jurisdiction reviews a motion for a new trial based on the federal standard. *Conte v. Gen. Housewares Corp.*, 215 F.3d 628, 637 (6th Cir. 2000). Under Federal Civil Rule 59, a new trial may be granted in a jury trial for "any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). According to the Sixth Circuit, "[a] new trial may be warranted under Rule 59 'when a jury has reached a seriously erroneous result as evidenced by . . . the verdict being against the weight of the evidence . . . or [] the trial being unfair to the moving party in some fashion, *i.e.*, the proceedings being influenced by prejudice or bias.'" *CFE Racing Prods., Inc. v. BMF Wheels, Inc.*, 793 F.3d 571, 584 (6th Cir. 2015) (quoting *Balsley v. LFP*,

Inc., 691 F.3d 747, 761 (6th Cir. 2012)). The “governing principle” in a court’s consideration of a Rule 59(a) motion “is whether, in the judgment of the trial judge, such course is required in order to prevent an injustice”. *Park W. Galleries v. Hochman*, 692 F.3d 539, 544 (6th Cir. 2012) (internal quotations and citations omitted).

To obtain a new trial on grounds of unfairness, the moving party must identify errors that impacted the parties’ substantial rights. *Walker v. Bain*, 257 F.3d 660, 670 (6th Cir. 2001) (citing Fed. R. Civ. P. 59, 61).¹ Stated differently, the identified errors must have been so prejudicial that a refusal to grant a new trial is “inconsistent with substantial justice.” *Burks v. O’Connor, Kenny Partners, Inc.*, 33 F. App’x 781, 783 (6th Cir. 2002) (internal citations omitted).

Moreover, when a claimed error relates to evidence admitted at trial, the moving party must demonstrate the claimed error was not harmless. *Cummins v. BIC USA, Inc.*, 727 F.3d 506, 510 (6th Cir. 2013). This is because “[t]he district court has broad discretion to determine questions of admissibility; an evidentiary ruling is not to be lightly overturned.” *Id.* Thus, even if there was an error in an evidentiary ruling, “a new trial will not be granted unless the evidence would have caused a different outcome at trial.” *Tompkin v. Philip Morris USA*, 362 F.3d 882, 891 (6th Cir. 2004).

1. Rule 61 provides:

Unless justice requires otherwise, no error in admitting or excluding evidence—or any other error by the court or a party—is ground for granting a new trial, for setting aside a verdict, or for vacating, modifying, or otherwise disturbing a judgment or order. At every stage of the proceeding, the court must disregard all errors and defects that do not affect any party’s substantial rights.

Fed. R. Civ. P. 61.

DISCUSSION

Plaintiff presents two arguments in favor of a new trial, both based on alleged prejudice caused by the Monograph. First, she argues unfair surprise in the use of the Monograph at trial. Second, she argues the admission of the Monograph without a sufficient foundation rises to the level of prejudicial error. The Court addresses each argument in turn.

Unfair Surprise

Plaintiff argues, in part, that “as best Plaintiff’s counsel can determine”, Defendants did not identify the Monograph in response to an interrogatory regarding what warnings information they provided to physicians. (Doc. 257-1, at 2-3). Defendants respond that the Monograph was properly disclosed and there is no unfair surprise.

Plaintiff did not raise this objection at trial and thus must show “gross injustice” to obtain a new trial on this basis. *Park W. Galleries, Inc. v. Hochman*, 692 F.3d 539, 548 (6th Cir. 2012) (“This court has also cited *Computer Systems Engineering* and *Nissho-Iwai Co.* approvingly to support the proposition that, in a civil action, a motion for a new trial will not be granted on grounds not called to the attention of the court during the trial itself unless failing to grant a new trial would result in a gross injustice.”) (citing *United States v. Walton*, 909 F.2d 915, 924 (6th Cir. 1990) (holding district court properly denied defendant’s motion for a new trial based on tax filing status when issue was raised for the first time in reply and no gross injustice would occur because defendant had access to the documents regarding filing status before trial started)).

However, as Defendants point out in response, the Bates number range of a copy of a version of the Monograph is included in the response to the very interrogatory Plaintiff cites. See Doc. 257-2, at 3-4 (identifying “ETH.MESH.03456774-ETH.MESH.03461142 (Prod. 34)”).

Doc. 259-1 (Monograph, labeled ETH.MESH.03460813-ETH.MESH.03460853).² Defendants further disclosed the Monograph in its pre-trial exhibit list. *See* Doc. 200-4, at 6-7 (Defendants' Exhibit List identifying two copies/versions of the Monograph as Exhibits 1156 and 1163).³ And Dr. Khandwala clearly disclosed the Monograph as part of the basis for his opinions regarding the adequacy of warnings. Doc. 259-3, at 11 (Dr. Khandwala opinion stating: "It's important to note that mesh erosion is warned about in the Prolift IFU, Surgeon's Monograph and Ethicon professional education materials.")

Thus, Plaintiff cannot argue there was any unfair surprise in the use of the Monograph at trial based on a failure to disclose the document, much less that failing to grant a new trial on this basis "would result in a gross injustice." (And indeed, she does not so argue in Reply).

Plaintiff further contends the Monograph was not properly disclosed as the basis for Dr. Sirls's opinions. *See* Doc. 257-1, at 7. This objection was addressed at trial and the Court determined:

If it's listed in the stuff he reviewed, I think it would be under the auspices of the totality of the training, educational materials. But if he didn't have that, then - - if she asks him did you receive this as part of your training and education, and he talks about the totality of the training and educational materials, I think that's okay.

(Tr. 1138). Dr. Sirls's 2017 report stated: "It is my opinion that the training and professional education for the Prolift System was well done, informative, and conveyed known risks of the Prolift system and other pelvic floor surgeries including dyspareunia and voiding dysfunction." (Doc. 257-3, at 56). Although the report itself did not identify the Monograph, Dr. Sirls prepared

2. This version of the Monograph was identified as Defendants' Exhibit 1163 in the instant case.
3. Exhibit 1156 is a black and white copy of a version of the Monograph with Bates numbering ETH.MESH.00658362-400. It bears no date stamp. Exhibit 1163 is a color copy of a Monograph with Bates numbering ETH.MESH.03460813-884. It contains hand-written editing notes and is stamped "Approved APR 13 2007 Marketing Services."

an addendum to his 2017 report in 2019, with which he included an updated Materials List, which included reference to the Monograph. *See* Doc. 259-2, at 100, 105 (Dr. Sirls Materials List identifying “2007 Prolift Surgeon Monograph” and “ETH.MESH.03460813-853 Prolift Surgeon’s Resource Monograph, approved 4.13.2007”).

Neither the 2017 nor 2019 report reference the Monograph specifically within the body. However, as discussed below, even if it were error to permit Dr. Sirls to testify regarding the Monograph, the Court finds it was harmless error.

Foundation

Plaintiff’s primary objection to the admission of the Monograph is her contention that Defendants failed to establish a sufficient foundation for its admission because Dr. Sirls recanted his foundational testimony on cross-examination. Defendants respond that the Monograph was properly admitted through Dr. Sirls, and even if it was not, any such error is harmless because (1) the Monograph could have been independently admitted through the testimony of Dr. Khandwala and (2) more broadly, Plaintiff cannot show any evidentiary error affected the outcome of the trial.

Dr. Sirls

On direct examination, Dr. Sirls testified he began using the Prolift in 2005 after receiving training, including training in a cadaver lab. (Tr. 1129, 1131). He further testified he served as a trainer for other physicians for the Prolift in one cadaver lab later. (Tr. 1232-33). He specifically testified as to Exhibit 1156, the Monograph:

Q: Doctor, I’ve just handed you what’s marked as Exhibit DX 1156. Could you please take a moment to look at it and let me know when you’re done.

A: Yes, I’m familiar with this.

Q: How are you familiar with DX 1156?

A: So this would have been the packet that was given to me when I trained in my Prolift cadaver lab.

Q: How do you know that?

A: Well, because it's the type of thing that would have been given in training like that. I have really no other way of getting it. I went to one cadaver lab, and when I came back, I put it on my shelf in my office because I thought it was a good resource.

Q: And were you the one who gave us a copy of that?

A: I believe that I was, yeah.

* * *

Q: Why did you save the monograph?

A: I had it as a reference so I could look at it. I thought I was really informative.

[Defendants' counsel]: Your Honor, at this time, defense moves for admission of Exhibit 1156 into evidence.

[Plaintiff's counsel]: Objection, Your Honor. It's hearsay.

[Defendants' counsel]: It came from our files, Your Honor. I think we've established that makes it not hearsay.

The Court: You got it as part of your training initially - - it's not training to be a trainer but when you were training to be a surgeon performing the Prolift procedure?

[Dr. Sirls]: Yes, sir.

The Court: I'm going to overrule the objection.

(Tr. 1139-40).

On cross-examination Dr. Sirls testified as follows, after being shown a January 2007 email with a draft monograph:

Q: Okay. If Dr. Miller had just drafted the Prolift monograph in January of 2007, that is not a document that you could have had in your possession when you learned how to use the Prolift in 2005, 2006, correct?

A: That's correct.

Q: Okay. So not only did you not have the slide deck when you got trained, you didn't have the monograph either, did you?

* * *

A: Yes.

Q: So your whole line of testimony about having the slide deck and having the monograph was just wrong, right?

A: My dates were wrong, but the information that I had at my fingertips at that time was this information. I just have the wrong dates. It's a long time ago. I'm sorry.

Q: You didn't have the monograph at all, did you?

A: The monograph just summarized the data that we knew. It's a summary.

Q: You didn't know the data when you trained to learn how to use the Prolift, correct?

A: There were some things that were extremely important that they taught us. The Prolift data I did not know.

* * *

Q: Also talked about the fact that when you, in 2005 or 2006, whenever you got your training, you didn't have the monograph, right, because it wasn't printed, correct?

A: Wouldn't have had that.

(Tr. 1203-04; 1218).

On re-direct, Dr. Sirls testified that cross-examination, including the questioning about an email with the draft Monograph, refreshed his memory:

Q: Once you saw those emails that you were shown, Exhibit 522 and 523, did that refresh your recollection of how the monograph and these slides, PX 64, ended up on your shelf?

A: Yeah, it's many years ago. I apologize, I just got the dates mixed up.

Q: So you would have used Exhibits 64 and 1156 at training that you did of other doctors who were doing surgical repairs of prolapse at those Ethicon sponsored professional education in 2007?

A: That's certainly possible.

[Plaintiff's counsel]: Objection Your Honor. Misstates his testimony.

The Court: I'll overrule the objection.

A: Yeah. Now that the dates are being laid out for me, that makes sense.

(Tr. 1232-34). This was consistent with his testimony on cross-examination regarding the slide deck: "I may have mixed up the years. It's been a long time ago. But this is the document that I had that I can recall. I thought that I trained with this, maybe I taught with this in the session that I proctored.". (Tr. 1196).

Although certainly not a model of clarity, Dr. Sirls' testimony establishes a foundation for the Monograph having been provided to him by Ethicon in 2007 despite his confusion about the dates. *See* Tr. 1139 ("[I]t's the type of thing that would have been given in training like that. I have really no other way of getting it."); Tr. 1232-34.

Dr. Khandwala

Even if it was error to admit the Monograph through Dr. Sirls's testimony, Plaintiff has not satisfied her burden to demonstrate prejudicial error.

First, Dr. Salil Khandwala specifically relied upon the Monograph in his expert report (Doc. 259-3, at 11)⁴ and testified regarding the Monograph and its use (Tr. 1460-61, 1472-78, 1531, 1550-64). Specifically, Dr. Khandwala testified:

Q: Now, doctor, when we started our discussion about the information that Ethicon provided or training of surgeons during the programs you were involved in, you mention the surgeon's resource monograph. Do you recognize Defense Exhibit 1156?

A: Yes.

Q: And what is it, other than the title that I just - -

A: So this is a group of doctors who are experienced surgeons who came together, same thing. This is how we learn to educate the others. To let us see what has all been put together. So this information through different conferences, different meetings, and then this brainstorming of these doctors who put together this compilation of information called surgeon's resource monograph in April, 2007.

What that goes about is information about what is this mesh, including the placement, that pearls that we discussed briefly and also possible complications, frequency of complications and how to manage those complications.

Q: Dr. Khandwala, how is this monograph made available to physicians?

A: If you remember those courses, the cadaver course, which is the lab course and also the proctorship, so these were available at both these courses for the attendees.

Q: And you said this was created - - I don't remember your exact words, sometime in April, 2007?

4. Dr. Khandwala's report states:

The fact that mesh exposure happened is not due to any intrinsic defect of the Prolift mesh system. As I discuss in my expert report, Prolift has an acceptably low rate of erosion in light of the benefit it provides the surgeon and the patient. It's important to note that mesh erosion is warned about in the Prolift IFU, Surgeon's Monograph and Ethicon professional education materials.

(Doc. 259-3, at 11).

A: That's correct.

Q: Okay. And so if a doctor attended an Ethicon-sponsored Prolift training, along the sorts we just described in April, 2008, would this document have been made available?

A: Yes.

Q: And how do you know that?

A: Because it was -- because I was part of that. You know, I was at these courses, and I knew that these documents were available and they always got this, and I would tell them look at this, what I just discussed, a lot of this information is in there. And of course, you've seen me operate and show you and now if you have any questions, you know, please call.

(Tr. 1472-74); *see also* Tr. 1478 (testifying that the Monograph was published in April 2007 and would have been available to anyone taking Prolift training thereafter).

Plaintiff responds that Dr. Khandwala acknowledged on cross-examination he was not the only physician who performed Prolift training, and had no personal knowledge of precisely what other trainers offered:

Q: All right. And for those -- the ones that you did, you weren't the [only] physician in the country that was performing training for Ethicon, right?

A: Correct.

Q: And so you don't really have any personal knowledge about training that was going on, other than the ones you proctored or were the preceptor for, correct?

A: I sort of now [sic] because I mentioned those summits and when the proctors would get together and we would discuss, so the team was the same. Of course, individual discussions that happened during the debrief sessions would be individualized, but overall, the concept remained the same, the didactics, the cadaver lab and debrief, and when it came for proctorship, it would be talking about the case, the case itself and then debrief.

Q: In terms of what your personal knowledge is and how that translates into your opinions in this case, your personal knowledge about what was

discussed at these training seminars, what you saw other doctors receive in terms of materials, that's what you visualized, right?

A: No, that's exactly what happened. If you look at the surgeon's resource monograph, it's a similar thing that doctors actually came together and published that document. That's what we would do. We would talk about these at the summit meetings and discuss them, what we were doing. So I would know what other preceptors were doing and the format was very similar.

Q: You don't have personal knowledge, as you sit here today, about anything else that was discussed at those training sessions because you weren't there, right?

A: I told you what I know. It's the same thing, it's similar, I mentioned that. I don't know exactly the verbiage that went on, but the team was similar.

Q: Okay. And in terms of Dr. Brown in this case, it's not your testimony that you trained her, right?

A: I'm not sure. I don't know how many people I've trained. I don't know each one of them.

Q: If the evidence has already come out at trial that you were not the trainer of Dr. Brown, then you don't have any information about what she received at the time of her training, correct?

A: I would say it's similar information. If you're telling me I was not the trainer, then I have nothing to argue against.

(Tr. 1505-07). Plaintiff focuses in large part on the fact that Dr. Khandwala did not train Plaintiff's implanting physician, Dr. Brown, and had no personal knowledge of what was offered at Dr. Brown's training specifically. But this speaks to the evidence overall, rather than the foundation for admission of the document. The Court finds that the Monograph could have been admitted through Dr. Khandwala's testimony. Thus, even if Dr. Sirls's testimony did not provide the proper foundation for admission of the Monograph, any such error was harmless. Plaintiff was free to argue – and in fact did argue – that Dr. Brown did not receive the Monograph. *See* Tr. 1745-48.

Second, although the Court acknowledges the emphasis Defendants placed on the Monograph, there was significant other evidence in the record that would support the jury's verdict *even absent* the Monograph. At trial there was testimony that warnings regarding the risks of Prolift were conveyed to implanting physicians through various avenues – the Instructions for Use, the Monograph, the slide deck presented at training, etc. Because a reasonable jury could have determined that the Prolift was not defective in its warnings even absent the Monograph, the Court finds Plaintiff has not shown the admission of the document was not harmless error.

Thus, the Court finds (1) there was no error in the admission of the Monograph, and (2) even if there was error, it was not so prejudicial that refusal to grant a new trial is “inconsistent with substantial justice”, *Burks*, 33 F. App’x at 783, or “would have caused a different outcome at trial”, *Tompkin*, 362 F.3d at 891.

CONCLUSION

For the foregoing reasons, good cause appearing, it is
ORDERED that Plaintiff’s Motion for New Trial (Doc. 257) be, and the same hereby is,
DENIED.

s/ James R. Knepp II
UNITED STATES DISTRICT JUDGE